

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA, *ex rel.*
JAMES F. ALLEN,

Relator – Plaintiff,

v.

ALERE HOME MONITORING, INC.;
ROCHE HEALTH SOLUTIONS, INC.;
ADVANCED CARDIO SERVICES;
CARDIOLINK CORP.; MDINR, LLC;
PATIENT HOME MONITORING, INC.;
TAMBRA INVESTMENTS, INC. d/b/a
REAL TIME DIAGNOSTICS; and
US HEALTHCARE SUPPLY, LLC,

Defendants.

Civil Action No. 1:16-CV-11372-PBS

**DEFENDANT PATIENT HOME MONITORING, INC.’S
REPLY MEMORANDUM OF LAW IN SUPPORT OF ITS
MOTION TO DISMISS THE FIRST AMENDED COMPLAINT**

PATIENT HOME MONITORING, INC.,

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Dated: April 6, 2018

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INTRODUCTION

Defendant Patient Home Monitoring, Inc. (“PHM”) submits this Reply Memorandum of Law in support of its Motion to Dismiss the First Amended Complaint (“Amended Complaint”) filed by relator James F. Allen (“Relator”). The Amended Complaint should be dismissed as to PHM for three reasons. First, despite filing a 59-page Amended Complaint, an 82-paragraph affidavit attaching 56 exhibits, and a 50-page Opposition, Relator still offers **no allegations whatsoever** concerning the “who, what, when, where, and how” of any allegedly fraudulent conduct and purportedly false claims or statements to the government **as to PHM**. Second, Relator still offers no plausible allegations in support of any contention that PHM’s enrollment form, which identifies the weekly-testing services PHM provides, somehow coerced, misled, or overpowered physicians into prescribing services that were not medically necessary. Third, Relator’s own theory – that all claims made by all defendants were false claims – sabotages his argument that he is not barred by the public disclosure doctrine and is the original source. For these reasons, and the reasons stated in PHM’s Memorandum of Law (Dkt. 92) and by the other co-defendants in this action, the Court should dismiss the Amended Complaint as to PHM.

ARGUMENT

I. Relator Still Fails to Meet the Requirements of Rule 9(b) Because He Nowhere Alleges Specific Facts Concerning Any Alleged False Claims by PHM.

Among all of Relator’s voluminous filings, Relator at no time has alleged specific facts supporting any claim that PHM submitted or caused to be submitted a false claim for reimbursement or false statement to Medicare or any government agency as required in False Claims Act cases under Rule 9(b). *See, e.g., United States ex rel. Hagerty v. Cyberonics*, 844 F.3d 26 (1st Cir. 2016) (affirming dismissal of FCA claim for allegedly promoting medically unnecessary device replacements for failure to allege fraud with required particularity). Relator

was never PHM's patient, and therefore none of his allegations concerning his experience with other service providers apply to PHM. Relator's physician, who also submitted an affidavit in support of the Amended Complaint, had no contact with PHM and makes no allegations about PHM. Relator identifies no patient, no physician, no specific claim, no date of claim, no specific service, and no date of service concerning any alleged false claim or statement made or caused to be made by PHM. Relator alleges no specific facts showing that PHM performed services without a prescription or certification from a patient's physician affirming that the requested services were medically necessary. Relator alleges no specific facts showing that PHM billed Medicare or any government agency for services that it did not perform. Relator alleges no specific facts showing that PHM made or used specific false statements in order to get a specific claim paid. Relator's claims against PHM are fatally flawed for failure to meet the requirements of Rule 9(b) and should be dismissed.

II. Relator States No Plausible Facts as to How Providing Physicians with an Enrollment Form Amounted to or Caused Any False Claim or Statement.

Relator offers no plausible allegations in support of his far-fetched theory that all claims submitted by all defendants – including PHM – were inherently false claims because defendants provided physicians with a form to use to enroll a patient for weekly testing services. Relator appears to argue that the very act of providing an enrollment form to physicians coerced, misled, or overpowered physicians into ordering services that were not medically necessary. He attempts to compare his theory about defendants' enrollment forms to false claims cases involving kickbacks, improperly bundled services or testing panels, blanket standing orders without individualized patient review, or "prescriptions" not written by physicians for a particular patient. *See* Opp'n at 16-17. Relator points to no case, however, where the mere use of an enrollment form completed by a physician for a specific service for a specific patient at a

specific time under specific circumstances, as here, amounted to a false claim or causing a false claim.

First, even a casual review of the PHM enrollment form provided by Relator (Self-Testing Referral Form/RX and Letter of Medical Necessity, attached to the Amended Complaint as Exhibit 5 (“PHM Form”)) reveals that Relator’s claims of coercion or fraud make no sense. The PHM Form, when completed by a physician, reflects a prescription and certification of medical necessity of a particular service for a particular patient with a particular diagnosis and target international normalized ratio (“INR”) range. The PHM Form asks for specific information about the patient, including name, date of birth, contact information, warfarin history, and target INR range. The PHM Form also requests specific information concerning the patient’s diagnosis, such as mechanical heart valve, atrial fibrillation, pulmonary embolism, or embolism and thrombosis. The PHM Form requests the physician’s contact information and reporting preference. Finally, the PHM Form requires the physician to certify the medical necessity of the weekly testing services for the patient.

Second, Relator also has offered no basis for concluding that the PHM Form – once completed and signed by a physician – is not and should not have been treated by PHM as a “bona fide order [...] for a real patient who actually needs it after some sort of examination or consultation by a licensed doctor.” *United States v. Smith*, 573 F.3d 639, 651 (8th Cir. 2009) (cited by Relator in Opp’n at 19) (affirming criminal conviction of defendant of various charges relating to unlawful distribution of controlled substances). In arguing that the enrollment forms were not real prescriptions, Relator cites to cases involving criminal enterprises illegally distributing controlled substances with fake prescriptions, which have absolutely no bearing on this case. Relator has presented **no facts** supporting the conclusory allegation that the PHM

Forms, once completed and signed by a doctor, were not bona fide orders for a real patient after examination or consultation by a licensed doctor for a service that the doctor certified was medically necessary. Relator has also not articulated any reason why PHM should not have treated the forms, once completed and signed, as valid prescriptions for the services for which they were presented.

Third, Relator provides no plausible allegations for how **any** physician – let alone **all** physicians – was misled or coerced by PHM's use of an enrollment form. He alleges no factual support for the contention that the form overpowered physicians into ordering services that were not medically necessary. He does not point to a single physician who claims to have been coerced or misled by the PHM Form. He fails to identify any services performed by PHM without a prescription or any prescription signed without a physician's authority. He also articulates no plausible theory for how providing an enrollment form for a physician to use is an inherently fraudulent act or automatically removed or curtailed the physician's independent judgment.

In light of this background, Relator's theory of liability is reduced to nothing more than an argument that PHM is required to provide in-home testing services to any patient who wishes to enroll, regardless of whether that patient requires weekly testing, monthly testing, or testing on any other schedule. This is simply not the law. It is well-established that providers cannot be compelled to deliver particular services to any particular patient. 42 U.S.C. § 1395a (Medicare "freedom of choice" provision); Dkt. 92 (p. 9 n.3, incorporating by reference Dkt. 58 (Section III.A.2, pp. 13-16)); Dkt. 129 (pp. 3-5). PHM has organized its business to provide a narrow service (in-home PT/INR testing) to a narrow group of patients (ones who require weekly

testing). Relator cannot state a FCA claim merely by complaining that PHM's services were not suitable for him.

III. Relator's Own Theory of Universal Fraud Undermines His Public Disclosure and Original Source Arguments.

While Relator fails to articulate any plausible basis for why anything PHM did or did not do led to a single false claim to the government, his own theory of ubiquitous false claims throughout the industry undermines his arguments as to the public disclosure bar and the original source exception. In addition to Relator's claims being barred because the purported "scheme" to enroll patients requiring weekly testing was disclosed on PHM's own website, Relator also cannot credibly claim that an allegedly universal practice in the PT/INR home-testing industry involving enrollment forms identifying frequent testing regimens was not publicly disclosed. *See United States ex rel. Winkelman v. CVS Caremark Corp*, 827 F.3d 201, 210 (1st Cir. 2016) (affirming district court's dismissal of FCA claim based on public disclosure bar). Furthermore, Relator is not the original source of this information that by his own allegations is universally known in the industry. *Id.* at 211. Relator's own theory in this action contradicts his assertion of being the original source of the information provided in the Amended Complaint. The Court should dismiss Relator's FCA claims because they are barred by the public disclosure doctrine and he does not qualify for the original source exception.

CONCLUSION

WHEREFORE, for the reasons stated above and in PHM's opening Memorandum of Law in Support of Its Motions to Dismiss, along with the arguments advanced by the other co-defendants in this action, defendant Patient Home Monitoring, Inc. respectfully requests that the Court dismiss the First Amended Complaint as to Patient Home Monitoring, Inc., with prejudice.

Respectfully submitted,

PATIENT HOME MONITORING, INC.,

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Dated: April 6, 2018

CERTIFICATE OF SERVICE

I certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on the date specified below.

Dated: April 6, 2018

/s/ Sara Jane Shanahan

Sara Jane Shanahan